



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Kable Bo Davis, PM03

From: Matthew Aubuchon, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Biologist

Date: 12/19/16

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 387376

Decision no.: Rereg

Submission no: Rereg

Action code: Rereg

Product Name: Bengal Roach Spray

EPA Reg. No or File Symbol: 68543-1

Formulation Type: Aerosol

Ingredients statement from the label with PC codes included:

Phenothrin 2.00% PC: 069005

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): Direct spray (1-3 seconds) of insects is instructed. Application rates of actual product are not disclosed; applications limited to once per day. For flying insects, spray overhead (3ft from surfaces) for 10 seconds per 1000 cubic feet of space. Keep treated areas closed for 30 minutes after spraying, then thoroughly ventilate before reentry. Do not treat more than once per day.

Use Patterns: Indoor use for pest hiding places, cracks and crevices, surfaces behind / under sinks, cabinets, and appliances, along baseboards and floors. Locations include attics, crawl spaces, storage areas, areas around doors and windows, and anywhere ants are trailing and / or entering the structure. Do not spray animals directly.

It is important to remove pets and people from the treatment area, turn off pilot lights, and cover food and utensils prior to application.

I. Action Requested: Reregistration efficacy review requested. MRIDs 45590804, 47370701, 44145101, and 45407804 are listed on the data matrix for this product and are reviewed here to determine if efficacy claims against ants, mosquitoes, flies, gnats, cockroaches, centipedes, and spiders are supported.

II. Background: Product specific data were called in for phenothrin to support the reregistration of this product.

III. MRID SUMMARY

MRID 45590804 contains 8 studies investigating efficacy against black widow spiders, brown dog ticks, cat fleas, centipedes, fire ants, mosquitoes (*Aedes aegypti* only), scorpions, and yellow jackets. Because the fire ants, mosquitoes, centipedes, and black widow spiders pertain to the subject product, data for flea, tick, yellow jackets, and scorpions are not reviewed here.

MRID 4737071 investigated the flushing efficacy of an aerosol spray against German cockroaches *Blatella germanica*. Test product for MRID was Bengal Product 2007A (EPA Reg. No. 68543-35).

MRID 44145101 investigated the efficacy of formulations F-2471 (2% phenothrin) and TOAPS (0.2% phenothrin; 1.6% piperonyl butoxide) against German cockroaches *Blatella germanica*, and harvester ants (no species specified). In separate tests, formulations F-2471 and OAT-II were tested against cat fleas *Ctenocephalides felis* and brown dog ticks *Rhipicephalus sanguineus*. Contents of the formulation OAT-II were not disclosed.

MRID 45407804 investigated direct spray applications of formulations F-21281 (0.4% phenothrin) and X-54241 (0.4% phenothrin; 1.6% MGK 264) against the human body louse *Pediculus humanus humanus*. Fabric surfaces were directly sprayed with test formulations, then mortality was recorded over a period of 24 hours.

45590804. Product Performance/Efficacy Testing in Support of Multicide Wasp & Hornet Killer 20861 EPA Reg. No. 1021-.

A. Liquid Formulation Efficacy – Black Widow Spiders

(1) non-GLP

(2) **Methods:** Three liquid formulations of the three substances were tested against the black widow spider (*Latrodectus mactans*). Test formulations consisted of the following: F-6643 (0.1% pyrethrin; 0.2% piperonyl butoxide; 0.334% MGK-264); F-2188 (0.12% phenothrin); OTI (2% pyrethrin).

(3) **Results:** No review was conducted on these data because none of the three test formulations matched the formulation of the subject product 68543-1.

(4) **Conclusion:** This study does not support that the subject product 68543-1 kills black widow spiders because the formulations of the test substances were liquid, whereas the subject product is an aerosol spray.

B. Pressurized Spray Efficacy – Centipedes

(1) non-GLP

(2) **Methods:** None of the four test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for centipede data (*Scolopendra hereos*). Test formulations consisted of the following: PN-1000-86B (0.25% resmethrin); CC-12625 (0.05% tetramethrin; 0.1% phenothrin); CC-12634 (0.05% tetramethrin; 0.1% phenothrin); OTA-II (0.2% pyrethrin; 1.6% piperonyl butoxide).

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-1 kills centipedes because the active ingredients of the test formulations did not match the subject product.

C. Fire Ant Spray Evaluation

(1) non-GLP

(2) **Methods:** None of the four test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for fire ant data (*Solenopsis invicta*). Test formulations consisted of the following: F-2577 (0.2% tetramethrin; 0.3% esfenvalerate); F-2695 (0.2% tetramethrin; 0.125% phenothrin); F-2611 (0.05% pyrethrins; 0.1% piperonyl butoxide; 0.167% MGK®264; 0.1% esfenvalerate); F-27301 (0.1% ETOC; 0.5% MGK®264).

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills fire ants because the active ingredients of the test formulations did not match the subject.

D. Pressurized Spray Efficacy – Mosquitoes

(1) non-GLP

(2) **Methods:** None of the three test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for mosquito data (*Aedes aegypti*). Test formulations consisted of the following: TL-4485 (0.1% phenothrin; 0.075% ETOC; 0.5% piperonyl butoxide); TOAPS (0.2% pyrethrin; 1.6% piperonyl butoxide); F-2086 (0.2% phenothrin; 0.2% tetramethrin).

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-1 kills mosquitoes because the active ingredients of the test formulations did not match the subject product.

MRID 45590804: This study is **unacceptable** and should be removed from the data matrix for 68543-1. Test formulations contained different active ingredients, multiple active ingredients, and/or synergists. Therefore, efficacy data could not be bridged to support claims on subject product 68543-1.

47370701. Test Flushing Efficacy of an Aerosol Spray against German Cockroaches

(1) GLP

(2) **Methods:** Material tested for this trial was Bengal Roach Spray (68543-1) containing 2% phenothrin. The trial was conducted with 5 replicates of IO male German cockroaches approximately 12 weeks old. Cockroaches were placed in a circular, vertical harborage of cardboard 1.5" in diameter and 6" tall. Cockroaches were allowed to acclimate for ca 2 hours. Immediately prior to treatment application, the harborage exit doors were provided at the top and bottom of the harborage. The harborage was sprayed from 24" with approximately 1 g of product. Flushing time of each cockroach was recorded fifteen minutes post-application, as were 2-hour knockdown and 24-hour mortality.

(3) **Results:** Flushing efficacy was highly variable (30%-100%) with average flushing efficacy around 50%. Two-hr. knockdown (KD) was recorded at 100% with 24-hr. mortality averaging around 50%. Reported 24-hr. mortality of 98% resulted from combining dead and moribund cockroaches. Control mortality was within acceptable range.

(4) **Conclusion:** This study does not support kills claims against German cockroaches. Study did not achieve an acceptable level of mortality against German cockroaches. Moribund and mortality counts should not be combined. There are no flushing claims on the label of the subject product, therefore flushing results do not apply.

MRID 47370701: This study is **unacceptable** and should be removed from the data matrix for product 68543-1. Moribund and mortality data were combined and therefore obscured actual efficacy of ~50% of the subject product. Kills claims against German cockroaches are not supported.

44145101. Multicide® Intermediate 2471 EPA File Symbol 1021-1557 Product Performance / Efficacy Reports

A. German Cockroaches

- (1) Non-GLP
- (2) **Methods:** Direct spray applications of formulations F-2471 (2% phenothrin) and TOAPS (0.2% phenothrin; 1.6% piperonyl butoxide) were conducted against German cockroach nymphs *Blatella germanica*. Although ten replications were conducted, the number of roach nymphs per replicate was not disclosed. Active ingredient(s) of the formulation OAT-II were not disclosed.
- (3) **Results:** Efficacy of F-2471 against German cockroach nymphs could not be determined because counts of moribund and dead were combined into a single metric at 24h and 48h. The reviewer could not determine the true mortality of the test product. The methods section did not disclose whether or not test roaches were moved to a clean container after being sprayed with the test product. As a result, test exposure could not be evaluated by the reviewer. Efficacy results for TOAPS and OAT-II were not reviewed because the respective test products contained synergists and active ingredients were unknown.
- (4) **Conclusion:** Results are **unacceptable** and do not sufficiently demonstrate efficacy against German cockroaches. Exposure to the test material could not be determined, number of roaches was not disclosed, and moribund plus dead data counts were combined into a single metric.

B. Harvester Ants

- (1) Non-GLP
- (2) **Methods:** Direct spray applications of formulations F-2471 (2% phenothrin) and TOAPS (0.2% phenothrin; 1.6% piperonyl butoxide) were conducted against harvester ants (no species specified). Details regarding the methodology were not disclosed in MRID. An external document was cited as source for methods. Five replicates of ten (10) ants were placed in a petri dish, sprayed, then transferred into a clean dish after 30 seconds.
- (3) **Results:** Efficacy of F-2471 against harvester ants could not be determined because counts of moribund and dead were combined into a single metric at 24h and 48h. The reviewer could not determine the true mortality of the test product. As a result, test exposure could not be evaluated by the reviewer. Efficacy results for TOAPS and OAT-II were not reviewed because the respective test products contained synergists and active ingredients were unknown.
- (4) **Conclusion:** Results are **unacceptable** and do not sufficiently demonstrate efficacy against harvester ants. Test species was not disclosed; moribund and dead data counts were combined into a single metric.

MRID 41445101 is classified as **unacceptable** and does not support efficacy claims against German cockroaches and harvester ants. Therefore, MRID 41445101 should be removed from the data matrix.

45407804. Multicide® Lice and Dust Mite Spray 27911 EPA Reg No. 1021- Product Performance / Efficacy Reports.

- (1) Non-GLP
- (2) **Methods:** Direct spray applications of formulations F-21281 (0.4% phenothrin) and X-54241 (0.4% phenothrin; 1.6% MGK 264) were conducted against the human body louse *Pediculus humanus humanus*. Fabric surfaces were directly sprayed with test formulations, then mortality was counted over a period of 24 hours.
- (3) **Results:** Efficacy results from MRID 45407804 were not assessed by the reviewer for the following reasons:
1) Active ingredients within test formulation X-54241 contained a synergist which is not present in product 68543-1; 2) There are no claims against human body lice on product label 68543-1.

- (4) **Conclusion:** Study was not reviewed. Results are not applicable.

MRID 45407804 is classified as **unacceptable** because it does not pertain to the subject product 68543-1. The active ingredients of the test formulations contained a synergist and there are no claims against human body lice on the label. Therefore, MRID 45407804 should be removed from the data matrix.

IV. EXECUTIVE SUMMARY

MRID 45590804: This study is **unacceptable** and should be removed from the data matrix for 68543-1. Test formulations contained different active ingredients, multiple active ingredients, and/or synergists. Therefore, efficacy data could not be bridged to support claims on subject product 68543-1.

MRID 47370701: This study is **unacceptable** and should be removed from the data matrix for product 68543-1. Moribund and mortality data were combined and therefore obscured actual efficacy of ~50% of the subject product. Kills claims against German cockroaches are not supported.

MRID 41445101 is classified as **unacceptable** and does not support efficacy claims against German cockroaches and harvester ants. Therefore, MRID 41445101 should be removed from the data matrix from 68543-1.

MRID 45407804 is classified as **unacceptable** because it does not pertain to the subject product 68543-1. The active ingredients of the test formulations contained a synergist and there are no claims against human body lice on the label. Therefore, MRID 45407804 should be removed from the data matrix.

V. LABEL RECOMMENDATIONS

- (1) Make the following changes to the Directions for Use:

- Delete directions for use against cockroaches, ants, mosquitoes, flies, gnats, house flies, spiders, general cockroaches, and centipedes (ant and spider DFU can remain if ants are qualified by “except fire, harvester, pharaoh, and carpenter ants” and spiders are qualified by “except black widow and brown recluse spiders”)

- (2) The following marketing claims are acceptable:

- Kills claims against crickets, sowbugs, firebrats, and silverfish.

- (3) The following marketing claims are unacceptable: All marketing claims against ants, mosquitoes, flies, gnats, house flies, spiders and centipedes are unacceptable.

- (4) The following MRIDs should be removed from the data matrix, as they are classified as “**unacceptable**” to support the product: 45590804; 41445101; 47370701, and 45407804.

- (5) Make other comments/recommendations as appropriate:

- An “ants” kills claim may be acceptable if it is qualified with a statement that kills claims exclude fire, harvester, pharaoh, and carpenter ants. A “spiders” kills claim may be acceptable if it is qualified with a statement that kills claim exclude brown recluse and black widow spiders.
- No house-fly data were submitted.
- Data for other roaches (Oriental, American, etc.) were not provided in any submitted studies, therefore broad roach claims are not supported.